

REMARKS**I. Status of the Claims**

Claims 24-29 are withdrawn.

Claims 1-12 are canceled.

Claims 13-30 are pending.

II. Rejections Withdrawn

Applicant thanks the examiner for withdrawing all previous rejections (Action pages 3-4).

III. Applicant is Surprised to Receive New Rejections**A. The Examiner Cites No Legal Support for A Position That Only Embodiments Can be Claimed**

Claims 13-23 and 30 were rejected due to lack of written description.

The examiner's reasons appear to narrow to the following reasons:

“because . . .the claimed screening method would require prior knowledge of the characteristics of both reactants ”

“specification does not sufficiently teach the relationship between biologic materials and known compounds”

“for a product that is already known, wherein use would be apparent”

“specification does not sufficiently teach how the product is being analyzed in order to determine that the known compound can be used as a drug or natural product”

(Action pages 4-8)

The examiner cites to examples in the specification, but does not relate them logically to her rejections. Also, no case law is cited that applicants are bound to claim only embodiments. The invention is clearly defined as a method and a kit useful to those of skill in the art.

The **written description** requirement is satisfied by the applicant's disclosure of such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. Put another way, one skilled in the art, reading the original disclosure, must reasonably **discern** the limitation at issue in the claims. *Crown Operations Int'l, LTD v. Solutia Inc.*,

289 F.3d 1367, 2002 (Fed. Cir., May 13, 2002, Decided) *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997)

The purpose of the "adequate **written description** requirement" is to ensure that the inventor had possession of the claimed subject matter at the time the application was filed. If a person of ordinary **skill** in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate **written description** requirement is met. *In re Alton*, 76 F.3d 1168, 1996 U.S. App. LEXIS 1691 (Fed. Cir., February 5, 1996, DECIDED).

Compliance with the written description requirement is essentially a fact-based inquiry that will necessarily vary depending on the nature of the invention claimed." *Enzo Biochem*, 296 F.3d at 1324, 63 USPQ2d at 1613. The present invention is for a **general method** and does not require demonstrating all possible uses.

B. The Examiner is Incorrect in Requesting "Essential Steps" To Be Added To The Claims

Claims 13-23 and 30 were rejected as omitting essential steps.

Section 2172.01 was cited by the examiner as the basis for the rejection (office action of 9/23/03, page 7, paragraph No. 13) under 35 USC 112, 2nd, that claims 13-22 and 30 are incomplete for omitting essential steps.

The examiner has overlooked the first few words in Section 2172.01 which states "[a] claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may be rejected...." The steps stated in the rejection as having been omitted are not "disclosed" in our specification **as essential** and there are no statements of record that such steps are essential.

Accordingly, the rejection should be withdrawn.

C. A Declaration Under 35 C.F.R. § 1.132 is Provided to Remove van Breemen *et al.*

A Declaration from the inventor attests that the work in the publication cited (van Breemen *et al.*, 1998) is not "by another" so the 102 (a) rejection of claims 13-22 should be withdrawn. If necessary, Declarations from those of skill in the art can be provided to show that possession of the invention is clear from the specification.

IV. Summary and Conclusion

This application has been pending since 1999 and, as demonstrated in the record, has suffered from turnover of examiners and supervisors, and the inequity of having issues rehashed over time after being resolved. The purpose of the patent laws are not merely be obstructive.

After the interview of December 22, 2003 and the amendment of December 18, 2003 all pending rejections were withdrawn. Yet the examiner come back with more legally unsupportable rejections.

Another interview is requested before applicant appeals if there are still 112 rejections.

Please contact applicants' representative if you have any questions.

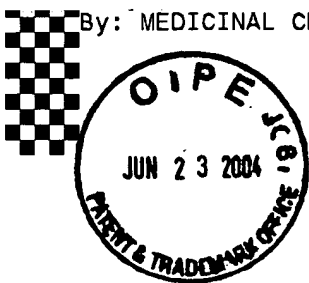
No other fees are believed due at this time, however, please charge any deficiencies or credit any overpayments to deposit account number 12-0913 with reference to our attorney docket number (21419/90386).

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Alice O. Martin".

Alice O. Martin
Registration No. 35,601

June 23, 2004



Date

6/23/04

Express Mail No.

99 0038315USCertificate of Mailing by Express Mail

I hereby certify that the below identified Application and attached documents, pursuant to 37 CFR 1.10, are being deposited as "Express Mail" this date with the United States Postal Service in an envelope addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231

By

Signature of person depositing Express Mail

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: 21726/90386

In re patent application of:

Richard B. van Breemen and Judy L. Bolton

Serial No. 09/471,523

Group Art Unit: 1639

Filed: December 23, 1999

Examiner: My-Chau T Tran

For: SCREENING OF XENOBIOTICS AND ENDOGENOUS COMPOUNDS
FOR METABOLIC TRANSFORMATION, FORMATION OF TOXIC
METABOLITES, AND BIOAVAILABILITY

DECLARATION UNDER 37 C.F.R. §1.132

Sir:

I, Richard van Breemen, hereby declare that:

1. I am a co-inventor in the above-captioned application ("the application").
2. I am also a co-author of an article entitled "Metabolic Screening Using On-line Ultrafiltration Mass Spectrometry". Drug Metabolism and Disposition, 26: 85-90 (1998) used as basis for a rejection by the U.S. Patent Office.

3. I have read the Office Action of March 23, 2004 in connection with the application wherein the Examiner rejected claims 13-22 under 35 USC §102(a) over van Breemen *et al.*

Regarding the material reported in van Breemen *et al.*

4. Nothing in the publication which relates to the application was invented by anyone but the inventive entity of the present application.
5. The following co-author of the van Breemen paper worked under my direction and control and followed by instructions:

Dejan Nikolic was my graduate student. He performed experiments as instructed that used the technology invented by Judy Bolton and myself.

6. I further declare that all statements made herein of my own knowledge are true, and that all statements made on the information and belief are believed to be true; and further that these statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements and the like so made may jeopardize the validity of this declaration, the subject application or any patent issuing thereon.

DATE

June 23, 2004

Richard B. van Breemen
Richard B. van Breemen